

## SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

### PART 70—INTERSTATE QUARANTINE

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AUTHORITY: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361-369, PHS Act, as amended (42 U.S.C. 264-272); 31 U.S.C. 9701.

SOURCE: 65 FR 49908, Aug. 16, 2000, unless otherwise noted.

#### § 70.1 General definitions.

As used in this part, terms shall have the following meaning:

(a) *Communicable diseases* means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(b) *Communicable period* means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(c) *Conveyance* means any land or air carrier, or any vessel as defined in paragraph (h) of this section.

(d) *Incubation period* means the period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(e) *Interstate traffic* means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(i) From a point of origin in any State or possession to a point of des-

tination in any other State or possession; or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(f) *Possession* means any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(g) *State* means any State, the District of Columbia, Puerto Rico, and the Virgin Islands.

(h) *Vessel* means any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

#### § 70.2 Measures in the event of inadequate local control.

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or

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articles believed to be sources of infection.

#### § 70.3 All communicable diseases.

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession, or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

#### § 70.4 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

#### § 70.5 Certain communicable diseases; special requirements.

The following provisions are applicable with respect to any person who is in the communicable period of cholera, plague, smallpox, typhus or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof:

##### (a) *Requirements relating to travelers.*

(1) No such person shall travel from one State or possession to another, or on a conveyance engaged in interstate traffic, without a written permit of the Surgeon General or his/her authorized representative.

(2) Application for a permit may be made directly to the Surgeon General or to his/her representative authorized to issue permits.

(3) Upon receipt of an application, the Surgeon General or his/her authorized representative shall, taking into consideration the risk of introduction, transmission, or spread of the disease from one State or possession to another, reject it, or issue a permit that may be conditioned upon compliance with such precautionary measures as he/she shall prescribe.

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(4) A person to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances as required by its terms.

(b) *Requirements relating to operation of conveyances.* (1) The operator of any conveyance engaged in interstate traffic shall not knowingly:

(i) Accept for transportation any person who fails to present a permit as required by paragraph (a) of this section; or

(ii) Transport any person in violation of conditions prescribed in his/her permit.

(2) Whenever a person subject to the provisions of this section is transported on a conveyance engaged in interstate traffic, the operator thereof shall take such measures to prevent the spread of the disease, including submission of the conveyance to inspection, disinfection and the like, as an officer of the Public Health Service designated by the Surgeon General for such purposes deems reasonably necessary and directs.

#### § 70.6 Apprehension and detention of persons with specific diseases.

Regulations prescribed in this part authorize the detention, isolation, quarantine, or conditional release of individuals, for the purpose of preventing the introduction, transmission, and spread of the communicable diseases listed in an Executive Order setting out a list of quarantinable communicable diseases, as provided under section 361(b) of the Public Health Service Act. Executive Order 13295, of April 4, 2003, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov>, or at <http://www.archives.gov/federal/register>. If this Order is amended, HHS will enforce that amended order immediately and update this reference.

[68 FR 17559, Apr. 10, 2003]

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### § 70.7 Responsibility with respect to minors, wards, and patients.

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

### § 70.8 Members of military and naval forces.

The provisions of §§ 70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: *Provided*, That in the case of persons otherwise subject to the provisions of § 70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

### § 70.9 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to administer vaccines and/or other prophylaxis.

(b) A vaccination fee may be charged for individuals not enrolled in Medicare Part B to cover costs associated with administration of the vaccine and/or other prophylaxis. Such fee is to be collected at the time that the vaccine is administered. The vaccination fee, if imposed, is shown in the following table:

Vaccine	Effective dates	Amount
Fluarix .....	11/25/05	<sup>2</sup> \$25.00

<sup>1</sup> Continuing for one year.

<sup>2</sup> \$7.00 for the vaccine and \$18.00 for administration.

[70 FR 3493, Jan. 25, 2005]

## PART 71—FOREIGN QUARANTINE

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AUTHORITY: Secs. 215 and 311 of Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

SOURCE: 50 FR 1519, Jan. 11, 1985, unless otherwise noted.

### Subpart A—Definitions and General Provisions

#### § 71.1 Scope and definitions.

(a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or possessions of the United States. Regulations pertaining to preventing the interstate

spread of communicable diseases are contained in 21 CFR parts 1240 and 1250.

(b) As used in this part the term:

*Carrier* means a ship, aircraft, train, road vehicle, or other means of transport, including military.

*Communicable disease* means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

*Contamination* means the presence of undesirable substances or material which may contain infectious agents or their toxic products.

*Controlled Free Pratique* means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

*Deratting Certificate* means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and deratting of the ship.

*Deratting Exemption Certificate* means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and exemption from deratting of the ship which is rodent free.

*Detention* means the temporary holding of a person, ship, aircraft, or other carrier, animal, or thing in such place and for such period of time as may be determined by the Director.

*Director* means the Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative.

*Disinfection* means the killing of infectious agents or inactivation of their toxic products outside the body by direct exposure to chemical or physical agents.

*Disinfestation* means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents, present upon the person, the clothing, or the environment of an individual, or upon animals and carriers.

*Disinsection* means the operation in which measures are taken to kill the insect vectors of human disease present in carriers and containers.

*Educational purpose* means use in the teaching of a defined educational program at the university level or equivalent.

*Exhibition purpose* means use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

*Ill person* means a person who:

(1) Has a temperature of 100 °F. (or 38 °C.) or greater, accompanied by a rash, glandular swelling, or jaundice, or which has persisted for more than 48 hours; or

(2) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of a greater than normal (for the person) amount of loose stools.

*International Health Regulations* means the International Health Regulations of the World Health Organization, adopted by the Twenty-Second World Health Assembly in 1969, as amended by the Twenty-Sixth World Health Assembly in 1973, the Thirty-Fourth World Health Assembly in 1981, and as may be further amended.

*International voyage* means: (1) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or (2) in the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

*Isolation* means: (1) When applied to a person or group of persons, the separation of that person or group of persons from other persons, except the health staff on duty, in such a manner as to prevent the spread of infection; or (2) when applied to animals, the separation of an animal or group of animals

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from persons, other animals, or vectors of disease in such a manner as to prevent the spread of infection.

*Military services* means the U.S. Army, the U.S. Air Force, the U.S. Navy, and the U.S. Coast Guard.

*Scientific purpose* means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

*Surveillance* means the temporary supervision of a person who may have or has been exposed to a communicable disease.

*U.S. port* means any seaport, airport, or border crossing point under the control of the United States.

*United States* means the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

*Vector* means an animal (including insects) or thing which conveys or is capable of conveying infectious agents from a person or animal to another person or animal.

### § 71.2 Penalties.

Any person violating any provision of these regulations shall be subject to a fine of not more than \$1,000 or to imprisonment for not more than 1 year, or both, as provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

### § 71.3 Designation of yellow fever vaccination centers; Validation stamps.

(a) *Designation of yellow fever vaccination centers.* (1) The Director is responsible for the designation of yellow fever vaccination centers authorized to issue certificates of vaccination. This responsibility is delegated by the Director to a State or territorial health department with respect to yellow fever vaccination activities of non-Federal medical, public health facilities, and licensed physicians functioning within the respective jurisdictions of a State or territorial health department. Des-

ignation may be made upon application and presentation of evidence satisfactory to a State or territorial health department that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent, and pure yellow fever vaccine. Medical facilities of Federal agencies are authorized to obtain yellow fever vaccine without being designated as a yellow fever vaccination center by the Director.

(2) A designated yellow fever vaccination center shall comply with the instruction issued by the Director or by a delegated officer or employee of a State or territorial health department for the handling, storage, and administration of yellow fever vaccine. If a designated center fails to comply with such instruction, after notice to the center, the Director or, for non-Federal centers, a State or territorial health department, may revoke designation.

(b) *Validation stamps.* International Certificates of Vaccination against cholera and yellow fever issued for vaccinations performed in the United States shall be validated by:

(1) The Seal of the Public Health Service; or

(2) The Seal of the Department of State; or

(3) The stamp of the Department of Defense; or

(4) The stamp issued to the National Aeronautics and Space Administration; or

(5) The stamp issued by a State or territorial health department; or

(6) An official stamp of a design and size approved by the Director for such purpose.

## Subpart B—Measures at Foreign Ports

### § 71.11 Bills of health.

A carrier at any foreign port clearing or departing for any U.S. port shall not be required to obtain or deliver a bill of health.

### Subpart C—Notice of Communicable Disease Prior to Arrival

#### § 71.21 Radio report of death or illness.

(a) The master of a ship destined for a U.S. port shall report immediately to the quarantine station at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew (including those who have disembarked or have been removed) during the 15-day period preceding the date of expected arrival or during the period since departure from a U.S. port (whichever period of time is shorter).

(b) The commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report by radio 24 hours before arrival the number of cases (including zero) of diarrhea in passengers and crew recorded in the ship's medical log during the current cruise. All cases of diarrhea that occur after the 24 hour report must also be reported not less than 4 hours before arrival.

(Approved by the Office of Management and Budget under control number 0920–0134)

### Subpart D—Health Measures at U.S. Ports: Communicable Diseases

#### § 71.31 General provisions.

(a) Upon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States, as may exist when the carrier has on board individual(s) reportable in accordance with § 71.21 or meets the circumstances described in § 71.42. Carriers not subject to inspection under this section will be subject to sanitary inspection under § 71.41 of this part.

(b) The Director may require detention of a carrier until the completion

of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

#### § 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in an Executive Order, as provided under section 361(b) of the Public Health Service Act, he/she may isolate, quarantine, or place the person under surveillance and may order disinfection or disinfestation, fumigation, as he/she considers necessary to prevent the introduction, transmission or spread of the listed communicable diseases. Executive Order 13295, of April 4, 2003, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov> and [http://www.archives.gov/federal\\_register](http://www.archives.gov/federal_register). If this Order is amended, HHS will enforce that amended order immediately and update this reference.

(b) Whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention, disinfection, disinfestation, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.

[68 FR 17559, Apr. 10, 2003]

#### § 71.33 Persons: Isolation and surveillance.

(a) Persons held in isolation under this subpart may be held in facilities suitable for isolation and treatment.

(b) The Director may require isolation where surveillance is authorized in this subpart whenever the Director

considers the risk of transmission of infection to be exceptionally serious.

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and report, in person or by telephone, to the local health officer having jurisdiction over the areas to be visited, and report for medical examinations as may be required;

(2) Upon arrival at any address other than that stated as the intended destination when placed under surveillance, or prior to departure from the United States, inform, in person or by telephone, the health officer serving the health jurisdiction from which he/she is departing.

(d) From time to time the Director may, in accordance with section 322 of the Public Health Service Act, enter into agreements with public or private medical or hospital facilities for providing care and treatment for persons detained under this part.

(Approved by the Office of Management and Budget under control number 0920-0134)

[50 FR 1519, Jan. 11, 1985; 50 FR 3910, Jan. 29, 1985]

#### **§ 71.34 Carriers of U.S. military services.**

(a) Carriers belonging to or operated by the military services of the United States may be exempted from inspection if the Director is satisfied that they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40-12, Air Force Regulation No. 161-4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from inspection of carriers under this section, animals or articles on board shall be required to comply with the applicable requirements of subpart F of this part.

#### **§ 71.35 Report of death or illness on carrier during stay in port.**

The master of any carrier at a U.S. port shall report immediately to the

quarantine station at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew.

(Approved by the Office of Management and Budget under control number 0920-0134)

### **Subpart E—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection**

#### **§ 71.41 General provisions.**

Carriers arriving at a U.S. port from a foreign area shall be subject to a sanitary inspection to determine whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.

#### **§ 71.42 Disinfection of imports.**

When the cargo manifest of a carrier lists articles which may require disinfection under the provisions of this part, the Director shall disinfect them on board or request the appropriate customs officer to keep the articles separated from the other cargo pending appropriate disposition.

#### **§ 71.43 Exemption for mails.**

Except to the extent that mail contains any article or thing subject to restrictions under subpart F of this part, nothing in the regulations in this part shall render liable to detention, disinfection, or destruction any mail conveyed under the authority of the postal administration of the United States or of any other Government.

#### **§ 71.44 Disinsection of aircraft.**

(a) The Director may require disinsection of an aircraft if it has left a foreign area that is infected with insect-borne communicable disease and the aircraft is suspected of harboring insects of public health importance.

(b) Disinsection shall be the responsibility of the air carrier or, in the case of aircraft not for hire, the pilot in command, and shall be subject to monitoring by the Director.

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(c) Disinsection of the aircraft shall be accomplished immediately after landing and blocking.

(1) The cargo compartment shall be disinsected before the mail, baggage, and other cargo are discharged.

(2) The rest of the aircraft shall be disinsected after passengers and crew deplane.

(d) Disinsection shall be performed with an approved insecticide in accordance with the manufacturer's instructions. The current list of approved insecticides and sources may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333.

#### § 71.45 Food, potable water, and waste: U.S. seaports and airports.

(a) Every seaport and airport shall be provided with a supply of potable water from a watering point approved by the Commissioner of Food and Drugs, Food and Drug Administration, in accordance with standards established in title 21, Code of Federal Regulations, parts 1240 and 1250.

(b) All food and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, or waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

#### § 71.46 Issuance of Deratting Certificates and Deratting Exemption Certificates.

Valid Deratting Certificates or Deratting Exemption Certificates are not required for ships to enter a U.S. seaport. In accordance with Article 17 of the International Health Regulations, the Public Health Service may perform rodent infestation inspections and issue Deratting Certificates and Deratting Exemption Certificates.

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#### § 71.47 Special provisions relating to airports: Office and isolation facilities.

Each U.S. airport which receives international traffic shall provide without cost to the Government suitable office, isolation, and other exclusive space for carrying out the Federal responsibilities under this part.

#### § 71.48 Carriers in intercoastal and interstate traffic.

Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection as described in §§ 71.31 and 71.41 when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by insanitary conditions.

### Subpart F—Importations

#### § 71.51 Dogs and cats.

##### (a) Definitions.

As used in this section the term:

*Cat* means all domestic cats.

*Confinement* means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

*Dog* means all domestic dogs.

*Owner* means owner or agent.

*Valid rabies vaccination certificate* means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.



(b) *General requirements for admission of dogs and cats*—(1) *Inspection by Director*. The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.

(2) *Examination by veterinarian and confinement of dogs and cats*. When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for exposed animals*. (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.

(ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no

evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section shall be applicable to the examination or tests.

(4) *Sanitation*. When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.

(c) *Rabies vaccination requirements for dogs*. (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a dog unless the owner submits evidence satisfactory to the Director that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333); or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free; or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;

(ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;

(iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in

confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements.* The owner shall submit such certification regarding confinement and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats.* Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.

(f) *Requirements for dogs and cats in transit.* The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.

(g) *Disposal of excluded dogs and cats.* A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

(Approved by the Office of Management and Budget under control number 0920–0134)

**§ 71.52 Turtles, tortoises, and terrapins.**

(a) *Definitions.*

As used in this section the term:

*Turtles* includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order *Testudinata*, class *Reptilia*, except marine species (Families *Dermochelidae* and *Cheloniidae*).

(b) *Importation; general prohibition.* Except as otherwise provided in this section, live turtles with a carapace length of less than 4 inches and viable turtle eggs may not be imported into the United States.

(c) *Exceptions.* (1) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States, provided that such importation is not in connection with a business, and the importation is limited to lots of fewer than seven live turtles or fewer than seven viable turtle eggs, or any combinations of such turtles and turtle eggs totaling fewer than seven, for any entry.

(2) Seven or more live turtles with a carapace length of less than 4 inches, or seven or more viable turtle eggs or any combination of turtles and turtle eggs totaling seven or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(3) The requirements in paragraphs (c)(1) and (c)(2) of this section shall not apply to the eggs of marine turtles excluded from these regulations under § 71.52(a).

(d) *Application for permits.* Applications for permits to import turtles, as set forth in paragraph (c)(2) of this section, shall be made by letter to the Director, and shall contain, identify, or describe, the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities, the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria, and any other information and assurances the Director may require.

(e) *Criteria for issuance of permits.* A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria and on condition that the holder of the permit will provide such reports as the Director may require.

(f) *Interstate Regulations.* Upon admission at a U.S. Port, turtles and viable turtle eggs become subject to Food and Drug Administration Regulations (21 CFR 1240.62) regarding general prohibition.

(g) *Other permits.* Permits to import certain species of turtles may be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920-0134)

#### § 71.53 Nonhuman primates.

##### (a) *Definitions.*

As used in this section the term:

*Importer* means any person or corporation, partnership, or other organization, receiving live nonhuman primates from a foreign country within a period of 31 days, beginning with the importation date, whether or not the primates were held for part of the period at another location. The term *importer* includes the original importer and any other person or organization receiving imported primates within the 31-day period.

*Nonhuman primates* means all nonhuman members of the Order Primates, including, but not limited to, animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarin, lemurs, and lorises.

(b) *General prohibition.* No person or organization may import live nonhuman primates into the United States unless registered as an importer in accordance with applicable provisions of this section.

(c) *Uses for which nonhuman primates may be imported and distributed.* Live nonhuman primates may be imported into the United States and sold, resold, or otherwise distributed only for bona

fide scientific, educational, or exhibition purposes. The importation of nonhuman primates for use in breeding colonies is also permitted provided that all offspring will be used only for scientific, educational, or exhibition purposes. The maintenance of nonhuman primates as pets, hobby, or an avocation with occasional display to the general public is not a permissible use.

(d) *Registration of importers.* (1) Importers of nonhuman primates shall register with the Director in a manner prescribed by the Director.

(2) Documentary evidence that an importer will use all nonhuman primates solely for the permitted purposes is required.

(3) Registration shall include certification that the nonhuman primates will not be shipped, sold, or otherwise transferred to other persons or organizations without adequate proof that the primates will be used only for the permitted purposes.

(4) Registration shall be for 2 years, effective the date the application for registration is approved by the Director.

(5) Registration may be renewed by filing a registration application form with the Director not less than 30 days nor more than 60 days before expiration of the current registration.

(e) *Recordkeeping and reporting requirement for registered importers.* (1) Importers shall maintain records on each shipment of imported nonhuman primates received. The record on each shipment shall include the number of primates received, species, country of origin, date of importation, the number of primates in the shipment that die within 90 days after receipt, and cause(s) of deaths. If any primates in the shipment are sold or otherwise distributed within 90 days after receipt, the record shall include the number of primates in each shipment or sale, the dates of each shipment or sale, and the identity of the recipients. In addition, the record shall contain copies of documents that were presented to the importer to establish that the recipient would use the primates solely for the permitted purposes. The records shall be maintained in an organized manner in a central location at or in close

proximity to the importer's primate holding facility. The records shall be maintained for a period of 3 years and shall be available for inspection by the Director at any time.

(2) Importers shall report to the Director by telephone within 24 hours the occurrence of any illness in nonhuman primates that is suspected of being yellow fever, monkeypox, or Marburg/Ebola disease.

(3) Importers also shall report to the Director by telephone within 24 hours the occurrence of illness in any member of their staff suspected of having an infectious disease acquired from nonhuman primates.

(f) *Disease control measures.* Upon receipt of evidence of exposure of nonhuman primates to a communicable disease that may constitute a threat to public health, the Director may provide for or require examination, treatment, detention, isolation, seizure, or destruction of exposed animals. Any measures required shall be at the owner's expense.

(g) *Disposal of excluded nonhuman primates.* Nonhuman primate(s) excluded from the United States by provisions of this section shall, at the owner's option and expense, be exported, destroyed, or given to a scientific, educational, or exhibition facility under arrangements approved by the Director. If the owner fails to dispose of the nonhuman primate by one of the approved options or fails to select a method of disposal within 7 days, the Director will select the method of disposal. Pending disposal, the nonhuman primate(s) shall be detained at the owner's expense in custody of the U.S. Customs Service at the U.S. port.

(h) *Revocation of an importer's registration.* (1) An importer's registration may be revoked by the Director, upon notice to the importer holding such registration, if the Director determines that the importer has failed to comply with any applicable provisions of this section. The notice shall contain a statement of the grounds upon which the revocation is based.

(2) The importer may file an answer within 20 days after receipt of the notice. Answers shall admit or deny specifically, and in detail, each allegation in the notice. Allegations in the notice

not denied by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after receipt of the notice may be deemed an admission of all allegations of fact recited in the notice.

(3) The importer shall be entitled to a hearing with respect to the revocation upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of revocation. Failure to request a hearing shall be deemed a waiver of hearing and as consent to the submission of the case to the Director for decision based on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of available information.

(4) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this section, the Director shall render a final decision. A copy of such decision shall be served on the importer.

(5) An importer's registration which has been revoked may be reinstated by the Director upon inspection, examination of records, conference with the importer, and receipt of information and assurances of compliance with the requirements of this section.

(i) *Other permits.* In addition to the requirements under this section, permits to import certain species of nonhuman primates may also be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920-0134)

#### §71.54 Etiological agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be

released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

**§ 71.55 Dead bodies.**

The remains of a person who died of a communicable disease listed in § 71.32(b) may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated, or (c) accompanied by a permit issued by the Director.

**§ 71.56 African rodents and other animals that may carry the monkeypox virus.**

(a) *What actions are prohibited? What animals are affected?* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence) at 404-498-1633.

(ii) Your request must state the reasons why you need an exemption, de-

scribe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

(b) *What actions can CDC take?* (1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

(i) Issue an order causing an animal to be placed in quarantine,

- (ii) Issue an order causing an animal to be re-exported,
- (iii) Issue an order causing an animal to be destroyed, or
- (iv) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

(c) *How do I appeal an order?* If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

[68 FR 62369, Nov. 4, 2003]

## PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS<sup>1</sup>

Sec.

72.1 Definitions.

72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

72.4 Notice of delivery; failure to receive.

72.5 Requirements; variations.

72.6 Exemptions.

72.7 Penalties.

### APPENDIX A TO PART 72—SELECT AGENTS

AUTHORITY: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

SOURCE: 45 FR 48627, July 21, 1980, unless otherwise noted.

#### § 72.1 Definitions.

As used in this part:

<sup>1</sup>The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

*Biological product* means a biological product prepared and manufactured in accordance with the provisions of 9 CFR parts 102–104 and 21 CFR parts 312 and 600–680 and which, in accordance with such provisions, may be shipped in interstate traffic.

*Diagnostic specimen* means any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

*Etiologic agent* means a viable micro-organism or its toxin which causes, or may cause, human disease.

*Interstate traffic* means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

#### § 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

#### § 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of § 72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is

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packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

### BACTERIAL AGENTS

*Acinetobacter calcoaceticus*.  
*Actinobacillus*— all species.  
*Actinomycetaceae*— all members.  
*Aeromonas hydrophila*.  
*Arachnia propionica*.  
*Arizona hinshawii*— all serotypes.  
*Bacillus anthracis*.  
*Bacteroides* spp.  
*Bartonella*— all species.  
*Bordetella*— all species.  
*Borrelia recurrentis*, *B. vincenti*.  
*Brucella*— all species.  
*Campylobacter (Vibrio) fetus*, *C. (Vibrio) jejuni*.  
*Chlamydia psittaci*, *C. trachomatis*.  
*Clostridium botulinum*, *Cl. chauvoei*, *Cl. haemolyticum*, *Cl. histolyticum*, *Cl. novyi*, *Cl. septicum*, *Cl. tetani*.  
*Corynebacterium diphtheriae*, *C. equi*, *C. haemolyticum*, *C. pseudotuberculosis*, *C. pyogenes*, *C. renale*.  
*Edwardsiella tarda*.  
*Erysipelothrix insidiosa*.  
*Escherichia coli*, all enteropathogenic serotypes.  
*Francisella (Pasteurella) Tularensis*.  
*Haemophilus ducreyi*, *H. influenzae*.  
*Klebsiella*— all species and all serotypes.  
*Legionella*— all species and all Legionella-like organisms.  
*Leptospira interrogans*— all serovars.  
*Listeria*— all species.  
*Mimae polymorpha*.  
*Moraxella*— all species.  
*Mycobacterium*— all species.  
*Mycoplasma*— all species.  
*Neisseria gonorrhoeae*, *N. meningitidis*.  
*Nocardia asteroides*.  
*Pasteurella*— all species.  
*Plesiomonas shigelloides*.  
*Proteus*— all species.  
*Pseudomonas mallei*.  
*Pseudomonas pseudomallei*.  
*Salmonella*— all species and all serotypes.  
*Shigella*— all species and all serotypes.  
*Sphaerophorus necrophorus*.  
*Staphylococcus aureus*.  
*Streptobacillus moniliformis*.  
*Streptococcus pneumoniae*.  
*Streptococcus pyogenes*.  
*Treponema carereum*, *T. pallidum*, and *T. pertenue*.  
*Vibrio cholerae*, *V. parahemolyticus*.  
*Yersinia (Pasteurella) pestis*, *Y. enterocolitica*.

### FUNGAL AGENTS

*Blastomyces dermatitidis*.  
*Coccidioides immitis*.  
*Cryptococcus neoformans*.

*Histoplasma capsulatum*.  
*Paracoccidioides brasiliensis*.

### VIRAL AND RICKETTSIAL AGENTS

Adenoviruses—human—all types.  
Arboviruses—all types.  
*Coxiella burnetii*.  
Coxsackie A and B viruses—all types.  
Creutzfeldt—Jacob agent  
Cytomegaloviruses.  
Dengue viruses—all types.  
Ebola virus.  
Echoviruses—all types.  
Encephalomyocarditis virus.  
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.  
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).  
Herpesvirus—all members.  
Infectious bronchitis-like virus.  
Influenza viruses—all types.  
Kuru agent.  
Lassa virus.  
Lymphocytic choriomeningitis virus.  
Marburg virus.  
Measles virus.  
Mumps virus.  
Parainfluenza viruses—all types.  
Polioviruses—all types.  
Poxviruses—all members.  
Rabies virus—all strains.  
Reoviruses—all types.  
Respiratory syncytial virus.  
Rhinoviruses—all types.  
*Rickettsia*— all species.  
*Rochalimaea quintana*.  
Rotaviruses—all types.  
Rubella virus.  
Simian virus 40.  
Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.  
Vaccinia virus.  
Varicella virus.  
Variola major and Variola minor viruses.  
Vesicular stomatitis viruses—all types.  
White pox viruses.  
Yellow fever virus.<sup>2</sup>

(a) *Volume not exceeding 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers

<sup>2</sup>This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be packaged in accordance with the requirements contained in this part.

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may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

(b) *Volume greater than 50 ml.* Packaging of material in volumes of 50 ml. or more shall comply with requirements specified in paragraph (a) of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container

and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(c) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(d)(1) The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:



**ETIOLOGIC AGENTS**

**BIOMEDICAL  
MATERIAL**

**IN CASE OF DAMAGE  
OR LEAKAGE**

**NOTIFY DIRECTOR CDC  
ATLANTA, GEORGIA**

**404/633-5313**

(2) The color of material on which the label is printed must be white, the symbol red, and the printing in red or white as illustrated.

(3) The label must be a rectangle measuring 51 millimeters (mm) (2 inches) high by 102.5 mm (4 inches) long.

(4) The red symbol measuring 38 mm (1½ inches) in diameter must be cen-

tered in a white square measuring 51 mm (2 inches) on each side.

(5) Type size of the letters of label shall be as follows:

Etiologic agents—10 pt. rev.

Biomedical material—14 pt.

In case of damage or leakage—10 pt. rev.

Notify Director CDC, Atlanta, Georgia—8 pt. rev.

404-633-5313—10 pt. rev.



(e) *Damaged packages.* The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing an Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333, by telephone: (404) 633-5313. The carrier shall also notify the sender.

(f) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery:

*Coccidioides immitis.*

Ebola virus.

*Francisella (Pasteurella) tularensis.*

Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.

Herpesvirus simiae (B virus).

*Histoplasma capsulatum.*

Lassa virus.

Marburg virus.

*Pseudomonas mallei.*

*Pseudomonas pseudomallei.*

Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk Hemorrhagic fever, and Central European encephalitis viruses, Variola minor, and Variola major.

Variola major, Variola minor, and Whitepox viruses.

*Yersinia (Pasteurella) pestis.*<sup>3</sup>

#### § 72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain or reasonably believed to contain etiologic agents listed in § 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 (telephone (404) 633-5313). This section does not apply to select agents and toxins that are subject to requirements under the provi-

sions of 42 CFR 73.16 concerning transfers of select agents and toxins.

[45 FR 48627, July 21, 1980, as amended at 70 FR 13316, Mar. 18, 2005]

#### § 72.5 Requirements; variations.

The Director, Center for Disease Control, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

#### § 72.6 Exemptions.

(a) through (g) [Reserved]

(h) For purposes of 18 U.S.C. 175b, the exemptions to the list referred to in Appendix A constitute the exemptions set forth at 42 CFR 73.5 and 73.6.

[70 FR 13316, Mar. 18, 2005]

#### § 72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than \$500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

#### APPENDIX A TO PART 72—SELECT AGENTS

For purposes of 18 U.S.C. 175b, the list of select agents constitutes the list of select agents and toxins set forth at 42 CFR 73.3 and 73.4.

[70 FR 13316, Mar. 18, 2005]

### PART 73—SELECT AGENTS AND TOXINS

Sec.

73.1 Definitions.

73.2 Purpose and scope.

73.3 HHS select agents and toxins.

73.4 Overlap select agents and toxins.

<sup>3</sup>This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be transported in accordance with requirements contained in § 72.3(f).

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- 73.5 Exemptions for HHS select agents and toxins.
- 73.6 Exemptions for overlap select agents and toxins.
- 73.7 Registration and related security risk assessments.
- 73.8 Denial, revocation, or suspension of registration.
- 73.9 Responsible Official.
- 73.10 Restricting access to select agents and toxins; security risk assessments.
- 73.11 Security.
- 73.12 Biosafety.
- 73.13 Restricted experiments.
- 73.14 Incident response.
- 73.15 Training.
- 73.16 Transfers.
- 73.17 Records.
- 73.18 Inspections.
- 73.19 Notification of theft, loss, or release.
- 73.20 Administrative review.
- 73.21 Civil money penalties.

AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

SOURCE: 70 FR 13316, Mar. 18, 2005, unless otherwise noted.

### § 73.1 Definitions.

For purposes of this part:

*Administrator* means the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

*Animal and Plant Health Inspection Service (APHIS)* means the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

*Attorney General* means the Attorney General of the United States or any person authorized to act for the Attorney General.

*Biological agent* means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

*CDC* means Centers for Disease Control and Prevention of the Department of Health and Human Services.

*Diagnosis* means the analysis of specimens for the purpose of identifying or

confirming the presence or characteristics of a select agent or toxin provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

*Entity* means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

*HHS* means the Department of Health and Human Services.

*HHS Secretary* means the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

*HHS select agent and/or toxin* means a biological agent or toxin included in § 73.3.

*Overlap select agent and/or toxin* means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

*Principal investigator* means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

*Proficiency testing* means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

*Responsible Official* means the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

*Select agent and/or toxin* means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

*Specimen* means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

*State* means any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Toxin* means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or

protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

*United States* means all of the States.

*USDA* means the United States Department of Agriculture.

*Verification* means the demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

### § 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Biodefense Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

### § 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety.

(b) HHS select agents and toxins:

Abrin  
Cercopithecine herpesvirus 1 (Herpes B virus)  
*Coccidioides posadasii*  
Conotoxins  
Crimean-Congo haemorrhagic fever virus  
Diacetoxyscirpenol  
Ebola viruses  
Lassa fever virus  
Marburg virus  
Monkeypox virus  
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.  
Ricin  
*Rickettsia prowazekii*

*Rickettsia rickettsii*

Saxitoxin

Shiga-like ribosome inactivating proteins

South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])

Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)

*Yersinia pestis*

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nonfunctional HHS toxins.

(3) HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(e) An attenuated strain of a HHS select agent or toxin may be excluded from the requirements of this part based upon a determination that the

attenuated strain does not pose a severe threat to public health and safety.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at <http://www.cdc.gov/>.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any HHS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to CDC or APHIS.

(i) The seizure of Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal,

Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 70 FR 61049, Oct. 20, 2005]

#### § 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

*Bacillus anthracis*  
 Botulinum neurotoxins  
 Botulinum neurotoxin producing species of *Clostridium*  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mallei* (formerly *Pseudomonas mallei*)  
*Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)  
*Clostridium perfringens* epsilon toxin  
*Coccidioides immitis*  
*Coxiella burnetii*  
 Eastern Equine Encephalitis virus  
*Francisella tularensis*  
 Hendra virus  
 Nipah virus  
 Rift Valley fever virus  
 Shigatoxin  
 Staphylococcal enterotoxins  
 T-2 toxin  
 Venezuelan Equine Encephalitis virus

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nonfunctional overlap toxins.

(3) Overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; or 1,000 mg of T-2 toxin.

(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at <http://www.cdc.gov/>.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting overlap select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the select agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by the submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

**§ 73.5 Exemptions for HHS select agents and toxins.**

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law.

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis*. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary may exempt from the requirements of this part an investigational product that is, bears,

or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted. To apply for an exemption or an extension of an exemption, an individual or entity must submit a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the individual or entity in a response to a domestic or foreign public health emergency. A written decision granting or denying the request will be issued.

#### § 73.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law.

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary, after consultation with Administrator, may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin, may be exempted when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section

and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted. To apply for an exemption or an extension of an exemption, an individual or entity must submit a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the individual or entity in a response to a domestic or foreign public health emergency. A written decision granting or denying the request will be issued.

(f) Upon request of the Administrator, the HHS Secretary may exempt an individual or entity from the requirements of this part, for 30 calendar days if the Administrator has granted the exemption for agricultural emergency. The HHS Secretary may extend the exemption once for an additional 30 calendar days.

#### **§ 73.7 Registration and related security risk assessments.**

(a) Unless exempted under § 73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under § 73.6 or 9 CFR part 121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and Administrator.

(b) As a condition of registration, each entity must designate an individual to be its Responsible Official.



While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the Responsible Official.

(c)(1) As a condition of registration, the following must be approved by the HHS Secretary or Administrator based on a security risk assessment by the Attorney General:

- (i) The individual or entity,
- (ii) The Responsible Official, and
- (iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions:<sup>1</sup>

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

<sup>1</sup>These conditions may apply to more than one individual.

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(d) To apply for a certificate of registration that covers only HHS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC. To apply for a certificate of registration that does not cover only HHS select agents or toxins (*i.e.*, covers at least one overlap select agent and/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC or APHIS, but not both.

(e) Prior to the issuance of a certificate of registration, the Responsible Official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(f) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(g) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the Responsible Official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(h) A certificate of registration may be amended to reflect changes in circumstances (*e.g.*, replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

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(2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(i) An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.

(j) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(k) A certificate of registration will be valid for a maximum of three years.

### § 73.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the Responsible Official, or an individual who owns or controls the entity is within any of the categories described in 18 U.S.C. 175b,

(2) The individual or entity, the Responsible Official, or an individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5),

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(3) The individual or entity does not meet the requirements of this part, or

(4) It is determined that such action is necessary to protect public health and safety.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order,

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and

(3) Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 73.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

### § 73.9 Responsible Official.

(a) An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:

(1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General,

(2) Be familiar with the requirements of this part,

(3) Have authority and responsibility to act on behalf of the entity,

(4) Ensure compliance with the requirements of this part, and

(5) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to be an alternate Responsible Official, who may act for the Responsible Official in his/her absence.

These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.

(c) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Ebola viruses, Hendra virus, Marburg virus, Lassa fever virus, Nipah virus, Rift Valley fever virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, or *Yersinia pestis*. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(3) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(d) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.

**§ 73.10 Restricting access to select agents and toxins; security risk assessments.**

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may

not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) An individual's security risk assessment may be expedited upon written request by the Responsible Official and a showing of good cause (e.g., public health or agricultural emergencies, national security, or a short term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(f) An individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b,

(g) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as defined in 50 U.S.C. 1801), or

(2) It is determined such action is necessary to protect public health and safety.

(h) An individual may appeal the HHS Secretary's decision to deny, limit, or revoke access approval under § 73.20.

(i) Access approval is valid for a maximum of five years.

(j) The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

#### § 73.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control,

(2) Contain provisions for the control of access to select agents and toxins,

(3) Contain provisions for routine cleaning, maintenance, and repairs,

(4) Establish procedures for removing unauthorized or suspicious persons,

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes,

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records, and

(7) Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the HHS Secretary or Administrator,

(2) Allow individuals not approved for access from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, or other ac-

tivities not related to select agents or toxins only when continuously escorted by an approved individual,

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (*e.g.*, card access system, lock boxes),

(4) Inspect all suspicious packages before they are brought into or removed from the area where select agents or toxins are used or stored,

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release,

(6) Require that individuals with access approval from the HHS Secretary or Administrator refrain from sharing with any other person their unique means of accessing a select agent or toxin (*e.g.*, keycards or passwords),

(7) Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official:

(i) Any loss or compromise of keys, passwords, combination, etc.,

(ii) Any suspicious persons or activities,

(iii) Any loss or theft of select agents or toxins,

(iv) Any release of a select agent or toxin, and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised, and

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an entity or individual should consider, the document entitled "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. Morbidity and Mortality Weekly Report December 6, 2002; 51:RR-19:1-6." The document is available on the Internet at: <http://www.cdc.gov/mmwr>.

(f) The plan must be reviewed annually and revised as necessary. Drills or

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exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

### § 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider:

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories", including all appendices. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250-7954 or from the CDC Web site at <http://www.cdc.gov/>. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR parts 1910.1200 and 1910.1450.

(3) The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333 or from the CDC Web site at <http://www.cdc.gov/>. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be

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reviewed and revised, as necessary, after any drill or exercise and after any incident.

### § 73.13 Restricted experiments.

(a) An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.

(b) Restricted experiments:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD<sub>50</sub> < 100 ng/kg body weight.

(c) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

**§ 73.14 Incident response.**

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.<sup>2</sup> The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent and toxin and appropriate actions to contain such select agent or toxin.

(c) The incident response plan must also contain the following information:

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.),

(2) The name and contact information for the building owner and/or manager, where applicable,

(3) The name and contact information for tenant offices, where applicable,

(4) The name and contact information for the physical security official for the building, where applicable,

(5) Personnel roles and lines of authority and communication,

(6) Planning and coordination with local emergency responders,

(7) Procedures to be followed by employees performing rescue or medical duties,

(8) Emergency medical treatment and first aid,

(9) A list of personal protective and emergency equipment, and their locations,

(10) Site security and control,

<sup>2</sup>Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge, and

(12) Decontamination procedures.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

**§ 73.15 Training.**

(a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access.<sup>3</sup> In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

**§ 73.16 Transfers.**

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of

<sup>3</sup>The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard set forth at 29 CFR 1910.1030.

this section and must be authorized by CDC or APHIS prior to the transfer.<sup>4</sup>

(b) A transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements in this part,

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred, or

(iii) Is transferring the select agent or toxin from outside the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

(e) To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted.

(f) The recipient must submit a completed APHIS/CDC Form 2 within two business days of receipt of a select agent or toxin.

(g) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

(h) An authorization for a transfer shall be valid only for 30 calendar days

after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).

(i) The sender must comply with all applicable laws concerning packaging and shipping.

#### § 73.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.),

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) Where stored (e.g., building, room, and freezer),

(iv) When moved from storage and by whom and when returned to storage and by whom,

(v) The select agent used and purpose of use,

(vi) Records created under § 73.16 and 9 CFR 121.16 (Transfers),

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient, and

(viii) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release),

(2) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics,

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

<sup>4</sup>This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

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(iii) The initial and current quantity amount (*e.g.*, milligrams, milliliters, grams, etc.),

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom,

(v) Where stored (*e.g.*, building, room, and freezer),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(3) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry,

(5) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121.14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for three years and promptly produced upon request.

### § 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to in-

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spect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

### § 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

(b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information



(e.g., strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

#### § 73.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The HHS Secretary's decision constitutes final agency action.

#### § 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board have been dele-

gated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

## PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

Sec.

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APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of

## § 75.1

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1981, Pub. L. 97–35, 95 Stat. 599–600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

### § 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.

(b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing ionizing radiation. Nothing in these accreditation standards is intended to discriminate against proprietary schools.

### § 75.2 Definitions.

All terms not defined herein shall have the meaning given them in the Act. As used in this part:

*Accreditation*, as applied to an educational program, means recognition, by a State government or by a nongovernmental agency or association, of a specialized program of study as meeting or exceeding certain established qualifications and educational standards. As applied to a health care or educational institution, *accreditation* means recognition, by a State govern-

ment or by a nongovernmental agency or association, of the institution as meeting or exceeding certain established standards or criteria for that type of institution.

*Act* means the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10001–10008.

*Continuing competency* means the maintenance of knowledge and skills and/or demonstrated performance that are adequate and relevant to professional practice needs.

*Credentialing* means any process whereby a State Government or nongovernmental agency or association grants recognition to an individual who meets certain predetermined qualifications.

*Dental hygienist* means a person licensed by the State as a dental hygienist.

*Dental assistant* means a person other than a dental hygienist who assists a dentist in the care of patients.

*Educational program* means a set of formally structured activities designed to provide students with the knowledge and skills necessary to enter an occupation, with evaluation of student performance according to predetermined objectives.

*Energized laboratory* means any facility which contains equipment that generates ionizing radiation. This does not include facilities for training students when the equipment is not powered to emit ionizing radiation, e.g., practice in setting controls and positioning of patients.

*Formal training* means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

*Ionizing radiation* means any electromagnetic or particulate radiation (X-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles) which interacts with atoms to produce ion pairs in matter.

*Licensed practitioner* means a licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

*Licensure* means the process by which an agency of State government grants permission to persons meeting predetermined qualifications to engage in an occupation.

*Nuclear medicine technologist* means a person other than a licensed practitioner who prepares and administers radio-pharmaceuticals to human beings and conducts *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes.

*Permit* means an authorization issued by a State for specific tasks or practices rather than the entire scope of practice in an occupation.

*Radiation therapy technologist* means a person other than a licensed practitioner who utilizes ionizing radiation-generating equipment for therapeutic purposes on human subjects.

*Radiographer* means an individual other than a licensed practitioner who (1) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation, and (2) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiographers are distinguished from personnel whose use of diagnostic procedures is limited to a few specific body sites and/or standard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

*Radiologist* means a physician certified in radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

### § 75.3 Applicability.

(a) *Federal Government.* Except as provided in section 983 of the Act, the credentialing standards set out in the Appendixes to this part apply to those individuals who administer or propose to administer radiologic procedures, in each department, agency and instrumentality of the Federal Government as follows:

(1) *Radiographer Standards* apply to all individuals who are radiographers as defined in § 75.2 and who are not practitioners excepted by the Act.

(2) *Nuclear Medicine Technologist Standards* apply to all individuals who are nuclear medicine technologists as defined in § 75.2, who perform *in vivo* nuclear medicine procedures, and who are not practitioners excepted by the Act. For purposes of this Act, any administration of radiopharmaceuticals to human beings is considered an *in vivo* procedure.

(3) *Radiation Therapy Technologist Standards* apply to all individuals who perform radiation therapy and who are not practitioners excepted by the Act.

(4) *Dental Hygienist Standards* apply to all dental hygienists who perform dental radiography.

(5) *Dental Assistant Standards* apply to all dental assistants who perform dental radiography.

(6) The following persons are deemed to have met the requirements of these standards:

(i) Persons employed by the Federal government as radiologic personnel prior to the effective date of this regulation and who show evidence of current or fully satisfactory performance or certification of such from a licensed practitioner:

(ii) Uniformed military personnel who receive radiologic training from or through the Armed Forces of the United States and who meet standards established by the Department of Defense or components thereof, provided that those standards are determined by such Department or component to offer equivalent protection of patient health and safety:

(iii) Foreign national employed by the Federal government in positions outside of the United States who show evidence of training, experience, and

competence determined by the employing agency to be equally protective of patients health and safety; and

(iv) Persons first employed by the Federal government as radiologic personnel after the effective date of this regulation who (a) received training from institutions in a State or foreign jurisdiction which did not accredit training in that particular field at the time of graduation, or (b) practiced in a State or foreign jurisdiction which did not license that particular field or which did not allow special eligibility to take a licensure examination for those who did not graduate from an accredited educational program; provided that such persons show evidence of training, experience, and competence determined by the Office of Personnel Management or the employing agency to be equally protective of patient health and safety.

(7) The following persons are exempted from these standards:

(i) Persons who are trained to perform, or perform, covered radiologic procedures in emergency situations which preclude use of fully qualified personnel; and

(ii) Students in approved training programs.

(8) A department, agency, or instrumentality of the Federal government may, after consultation with the Secretary, use alternative criteria which it determines would offer equivalent protection of patient health and safety.

(b) *States.* The States may, but are not required to, adopt standards for accreditation and credentialing that are consistent with the standards set out in the appendixes to this part.

#### APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIOGRAPHERS

##### *A. Description of the Profession*

The radiographer shall perform effectively by:

1. Applying knowledge of the principles of radiation protection for the patient, self, and others.

2. Applying knowledge of anatomy, positioning, and radiographic techniques to accurately demonstrate anatomical structures on a radiograph.

3. Determining exposure factors to achieve optimum radiographic technique with a minimum of radiation exposure to the patient.

4. Examining radiographs for the purpose of evaluating technique, positioning, and other pertinent technical qualities.

5. Exercising discretion and judgment in the performance of medical imaging procedures.

6. Providing patient care essential to radiologic procedures.

7. Recognizing emergency patient conditions and initiating lifesaving first aid.

##### *B. Sponsorship*

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals;

(c) Medical schools;

(d) Postsecondary vocational/technical schools and institutions; and

(e) Other acceptable institutions which meet comparable standards.

3. The sponsoring institutions and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

##### *C. Instructional Facilities*

1. *General.* Appropriate classroom and clinical space, modern equipment, and supplies for supervised education shall be provided.

2. *Laboratory.* Energized laboratories utilized for teaching purposes shall be certified as required for compliance with Federal and/or State radiation safety regulations. The use of laboratories shall be governed by established educational objectives.

3. *Reference Materials.* Adequate up-to-date scientific books, periodicals, and other reference materials related to the curriculum and profession shall be readily accessible to students.

##### *D. Clinical Education*

1. The clinical phase of the educational program shall provide an environment for supervised competency-based clinical education and experience and offer a sufficient and well-balanced variety of radiographic examinations and equipment.

2. An acceptable ratio of students to registered technologists shall be maintained in the clinical teaching environment.

3. A clinical instructor(s), who shall be responsible for supervising students according to objectives, shall be identified for each primary clinical education center.

4. The maximum student enrollment shall not exceed the capacity recommended on the basis of volume and variety of radiographic procedures, resources, and personnel available for teaching purposes.

5. In programs where didactic and clinical experience are not provided in the same institution, accreditation shall be given only to the institution responsible for admissions, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the students in the clinical setting are educational. There shall be a uniform contract between the accredited institution and each of its affiliate hospitals, clearly defining the responsibilities and obligations of each.

#### *E. Curriculum*

1. The structure of the curriculum shall be based on not less than two calendar years of full-time study or its equivalent.

2. Instruction shall follow a planned outline that includes:

- (a) The assignment of appropriate instructional materials;
- (b) Classroom presentations, discussions and demonstrations; and
- (c) Examinations in the didactic and clinical aspects of the program.

3. All professional courses, including clinical education, must include specific curriculum content that shall include, but shall not be limited to:

- (a) Introduction to radiologic technology;
- (b) Medical ethics;
- (c) Imaging;
- (d) Radiographic processing technique;
- (e) Human structure and function;
- (f) Medical terminology;
- (g) Principles of radiographic exposure;
- (h) Radiographic procedures;
- (i) Principles of radiation protection;
- (j) Radiographic film evaluation;
- (k) Methods of patient care;
- (l) Pathology;
- (m) Radiologic physics; and
- (n) Radiation biology.

Related subjects added to the professional curriculum shall meet the requirements of the degree-granting institution.

#### *F. Finances*

Financial resources for operation of the educational program shall be assured through regular budgets, gifts, grants, endowments, or fees.

#### *G. Faculty*

1. *Program Director.* A program director shall be designated who is credentialed in ra-

diography. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiography shall not be adversely affected by educationally unrelated functions.

(a) *Minimum qualifications.* A minimum of two years of professional experience and proficiency in instructing, curriculum design, program planning, and counseling.

(b) *Responsibilities.* (1) The program director, in consultation with the medical director/advisor (G. 2.) shall be responsible for the organization, administration, periodic review, records, continued development, and general policy and effectiveness of the program.

(2) Opportunities for continuing education shall be provided for all faculty members.

2. *Medical Director/Medical Advisor*—(a) *minimum qualifications.* The medical director/medical advisor shall be a qualified radiologist, certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

(b) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for their achievement.

3. *Instructors.* All instructors shall be qualified through academic preparation and experience to teach the assigned subjects.

#### *H. Students*

##### ADMISSION

(a) Candidates for admission shall satisfy the following minimum requirements: Completion of four years of high school; successful completion of a standard equivalency test; or certification of equivalent education by an organization recognized by the United States Department of Education. Courses in physics, chemistry, biology, algebra, and geometry are strongly recommended.

(b) The number of students enrolled in each class shall be commensurate with the most effective learning and teaching practices and should also be consistent with acceptable student-teacher ratios.

#### *I. Records*

Records shall be maintained as dictated by good educational practices.

NOTE: Educational programs accredited by an organization recommended by the United States Department of Education are considered to have met these standards.

APPENDIX B TO PART 75—STANDARDS  
FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

*A. Sponsorship*

Sponsorship must be by an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. The formal training in dental radiography may be a part of a total program of dental hygiene education accredited by an organization recognized by the United States Department of Education.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental hygiene education programs or the State entity responsible for credentialing dental personnel in radiography.

*B. Curriculum*

Dental radiography training for dental hygienists must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental hygienists to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: Interaction of ionizing ra-

diation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: Sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Hygienists have the opportunity to develop competence in making radiographs. Faculty supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice where there is not direct supervision by faculty.

—Dental hygienists must demonstrate knowledge of radiation safety measures before making radiographs and, where possible, should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

#### *C. Student Evaluation*

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

#### *D. Faculty*

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity which approved the training program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

#### *E. Facilities*

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

#### *F. Learning Resources*

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards. Under existing licensure provisions in all States, becoming a dental hygienist requires graduation from a dental hygiene education program accredited by an organization recog-

nized by the United States Department of Education. In lieu of this requirement, Alabama accepts graduation from a State-approved preceptorship program.

### APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

#### *A. Sponsorship*

Sponsorship must be an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: Defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. Dental radiography training may be freestanding (as a continuing education course offered by State dental/dental auxiliary societies, or by dental/dental auxiliary education programs); or be a part of an educational program in dental assisting. Such dental assisting education programs may be accredited by an organization recognized by the United States Department of Education; or located in a school accredited by an institutional accrediting agency recognized by the United States Department of Education or approved by the State agency responsible for secondary and postsecondary education, or approved by a Federal agency conducting dental assistant education in that Agency.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental assisting education programs, or the State entity responsible for credentialing dental personnel in radiography.

#### *B. Curriculum*

Dental radiography training for dental assistants must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental assistants to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: Historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: Solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that

Dental Assistants have the opportunity to develop competence in making radiographs. The clinical experience may be conducted in the dental office in which the Dental Assistant is employed or is serving an externship. Faculty and/or employing dentist supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice when there is not direct supervision by faculty and/or the employing dentist.

—Dental Assistants must demonstrate knowledge of radiation safety measures before making radiographs, and where possible should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys, including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

#### C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

#### D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity (or Federal agency where appropriate) which approves the educational program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

#### E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment



must be available and of a quality that assures that films will not be damaged or lost.

#### F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

### APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

#### A. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

- (a) Community and junior colleges, senior colleges, and universities;
- (b) Hospitals and clinics;
- (c) Laboratories;
- (d) Medical schools;
- (e) Postsecondary vocational/technical schools and institutions; and
- (f) Other acceptable institutions which meet comparable standards.

3. The sponsoring institution and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

4. Responsibilities of the sponsor and each affiliate for program administration, instruction, supervision, etc., must be carefully described in written affiliation agreements.

#### B. Curriculum

Instruction must follow a plan which documents:

1. A structured curriculum including clinical education with clearly written syllabi which describe learning objectives and competencies to be achieved. The curriculum

shall be based on not less than one calendar year of full-time study or its equivalent.

2. The minimum professional curriculum that includes the following:

- (a) Methods of patient care;
- (b) Radiation safety and protection;
- (c) Nuclear medicine physics;
- (d) Radiation physics;
- (e) Nuclear instrumentation;
- (f) Statistics;
- (g) Radionuclide chemistry;
- (h) Radiopharmacology;
- (i) Departmental organization and function;
- (j) Radiation biology;
- (k) Nuclear medicine *in vivo* and *in vitro* procedures;
- (l) Radionuclide therapy;
- (m) Computer applications; and
- (n) Clinical practicum.

3. Assignment of appropriate instructional materials.

4. Classroom presentations, discussions, and demonstrations.

5. Supervised practice, experience, and discussions. This shall include the following:

- (a) Patient care and patient recordkeeping;
- (b) Participation in the quality assurance program;
- (c) The preparation, calculation, identification, administration, and disposal of radiopharmaceuticals;
- (d) Radiation safety techniques that will minimize radiation exposure to the patient, public, fellow workers, and self;
- (e) The performance of an adequate number and variety of imaging and non-imaging procedures; and
- (f) Clinical correlation of nuclear medicine procedures.

6. Evaluation of student's knowledge, problem-solving skills, and motor and clinical competencies.

7. The competencies necessary for graduation.

#### C. Resources

1. The program must have qualified program officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. The following program officials must be identified:

(a) *Program Director*—(1) *Responsibilities*. The program director of the educational program shall have overall responsibility for the organization, administration, periodic review, continued development, and general effectiveness of the program. The director shall provide supervision and coordination to the instructional staff in the academic and clinical phases of the program. Regular visits to the affiliates by the program director must be scheduled.

(2) *Qualifications*. The program director must be a physician or nuclear medicine technologist. The program director must

demonstrate proficiency in instruction, curriculum design, program planning, and counseling.

(b) *Medical Director*—(1) *Responsibilities*. The medical director of the program shall provide competent medical direction and shall participate in the clinical instruction. In multiaffiliate programs each clinical affiliate must have a medical director.

(2) *Qualifications*. The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board(s) of Nuclear Medicine, or Pathology, or Radiology, or possess suitable equivalent qualifications.

(c) *Clinical Supervisor*. Each clinical affiliate must appoint a clinical supervisor.

(1) *Responsibilities*. The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical affiliate.

(2) *Qualifications*. The clinical supervisor must be a technologist credentialed in nuclear medicine technology.

2. *Instructional Staff*—(a) *Responsibilities*. The instructional staff shall be responsible for instruction in the didactic and/or clinical phases of the program. They shall submit course outlines for each course assigned by the program director; evaluate students and report progress as required by the sponsoring institution; and cooperate with the program director in the periodic review and upgrading of course material.

(b) *Qualifications*. The instructors must be qualified, knowledgeable, and effective in teaching the subjects assigned.

(c) *Instructor-to-student ratio*. The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional development*. Accredited programs shall assure continuing education in the health profession or occupation and ongoing instruction for the faculty in curriculum design and teaching techniques.

3. Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources*. (a) *General*. Adequate classrooms, laboratories, and other facilities shall be provided.

(b) *Equipment and Supplies*. Modern nuclear medicine equipment, accurately calibrated, in working order, and meeting applicable Federal and State standards, if any, must be available for the full range of diagnostic and therapeutic procedures as outlined in the curriculum.

(c) *Reference Materials*. Reference materials appropriate to the curriculum shall be readily accessible to students.

(d) *Records*. Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources*. Instructional aids such as clinical materials, reference mate-

rials, demonstration and other multimedia materials must be provided.

#### D. Students

##### ADMISSION REQUIREMENTS

Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent. They shall have completed postsecondary courses in the following areas:

- (1) Human anatomy and physiology;
- (2) Physics;
- (3) Mathematics;
- (4) Medical terminology;
- (5) Oral and written communications;
- (6) General chemistry; and
- (7) Medical ethics.

Prerequisites may be completed during nuclear medicine training. Educational institutions such as junior colleges, universities, and technical vocational institutes may provide these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., two to four years).

#### E. Operational Policies

Students may not take the responsibility nor the place of qualified staff. However, students may be permitted to perform procedures after demonstrating proficiency, with careful supervision.

#### F. Continuing Program Evaluation

1. Periodic and systematic review of the program's effectiveness must be documented.

2. One element of program evaluation shall be the initial employment of graduates of the program.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

### APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

#### A. Sponsorship

1. Educational programs may be established in:

- (a) Community and junior colleges, senior colleges, and universities;
- (b) Hospitals, clinics, or autonomous radiation oncology centers meeting the criteria for major cancer management centers or meeting demonstrably equivalent standards;
- (c) Medical schools; and
- (d) Postsecondary vocational/technical schools and institutions.

2. The sponsoring institution and affiliates, if any, must be accredited by recognized agencies or meet equivalent standards. When more than one clinical education center is

used, each must meet the standards of a major cancer management center.

3. When didactic preparation and supervised clinical education are not provided in the same institution, accreditation must be obtained by the sponsoring institution for the total program. This institution will be the one responsible for admission, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the student in the clinical setting are educational. There shall be a uniform, written, affiliation agreement between the accredited institution and each clinical education center, clearly defining the responsibilities and obligations of each.

#### *B. Curriculum*

Educational programs of 24 months and 12 months or their equivalents may be developed. A 24-month program shall admit those candidates with a high school diploma (or equivalent) as outlined in D.1. The 12-month program shall be designed for those students admitted with backgrounds as outlined in D.2.

Instruction must follow a plan which documents:

1. A structured curriculum with clearly written course syllabi which describe competencies and learning objectives to be achieved. The curriculum shall include but not necessarily be limited to the following:

- (a) Orientation to radiation therapy technology;
- (b) Medical ethics and law;
- (c) Methods of patient care;
- (d) Medical terminology;
- (e) Human structure and function;
- (f) Oncologic pathology;
- (g) Radiation oncology;
- (h) Radiobiology;
- (i) Mathematics;
- (j) Radiation physics;
- (k) Radiation protection;
- (l) Radiation oncology technique;
- (m) Radiographic imaging; and
- (n) Clinical dosimetry.

The curriculum must include a plan for well-structured competency-based clinical education.

2. Assignment of appropriate instructional materials.

3. Classroom presentations, discussions, and demonstrations.

4. Supervised clinical education and laboratory practicum.

5. Evaluation of students to assess knowledge, problem-solving skills, and motor and clinical competencies.

6. Program graduates must demonstrate competencies including, but not limited to, the following:

- (a) Practice oral and written communications;

- (b) Maintain records of treatment administered;

- (c) Perform basic mathematical functions;

- (d) Demonstrate knowledge of human structure, function, and pathology;

- (e) Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;

- (f) Provide basic patient care and cardiopulmonary resuscitation;

- (g) Deliver a planned course of radiation therapy;

- (h) Verify physician's prescribed course of radiation therapy and recognize errors in computation;

- (i) Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;

- (j) Produces and utilize immobilization and beam directional devices;

- (k) Prepare commonly used brachytherapy sources;

- (l) Demonstrate knowledge of methods of calibration of equipment, and quality assurance;

- (m) Prepare isodose summations;

- (n) Detect malfunctioning equipment;

- (o) Apply rules and regulations for radiation safety, and detect defects which might pose a radiation hazard;

- (p) Understand the function of equipment and accessories;

- (q) Demonstrate knowledge of methods of continuing patient evaluation (follow up);

- (r) Apply wedge and compensating filters;

- (s) Recognize patients' clinical progress, complications, and demonstrate knowledge of when to withhold treatment until consultation with the physician; and

- (t) Interact with patients and families concerning the physical and psychological needs of patients.

#### *C. Resources*

1. *Program Officials.* The program must have a qualified program official or officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. A program director is necessary; other program officials may be required.

(a) *Program Director—(1) Responsibilities.*

—The director of the educational program shall be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiation therapy technology shall not be adversely affected by educationally unrelated functions.

—In a college-sponsored program, or a hospital-sponsored multiple affiliate program, the program director shall be an employee of the sponsoring institution. A schedule of regular affiliate visits must be maintained.

(2) *Qualifications.*

- Must be a technologist qualified in radiation therapy technology and educational methodologies.
- Must be credentialed in radiation therapy technology or possess suitable equivalent qualifications.
- Must have at least two years' experience as an instructor in an accredited educational program.

(b) *Clinical Supervisor.* Each clinical education center shall appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical education center.

(2) *Qualifications.* Must be a technologist, with suitable experience, qualified in radiation therapy technology and educational methodologies and must be credentialed in radiation therapy technology.

(c) *Medical Director/Medical Advisor—*

(1) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for achievement.

(2) *Qualifications.* The medical director/medical advisor shall be a qualified radiation oncologist certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

2. *Instructional Staff—* (a) *Responsibilities.* The instructional staff shall be responsible for submitting course outlines for each course assigned by the program director; evaluating students and reporting progress as required by the sponsoring institution; and cooperating with the program director in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be individually qualified, must be effective in teaching the subjects assigned, and must meet the standards required by the sponsoring institution.

(c) *Instructor-to-Student Ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional Development.* Programs shall have a policy that encourages continuing education in radiation therapy technology and assures ongoing instruction for the faculty in curriculum design and teaching strategies.

3. *Financial Resources.* Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources—*(a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided. All affiliated institutions shall provide space required for these facilities.

(b) *Equipment and Supplies.* Appropriate modern equipment and supplies in sufficient quantities shall be provided.

(c) *Laboratory.* Energized laboratories must meet Federal and/or State radiation and safety regulations.

(d) *Reference Materials.* An adequate supply of up-to-date books, periodicals, and other reference materials related to the curriculum and the profession shall be readily available to students.

(e) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided.

D. *Students*

## ADMISSION

1. Applicants must be high school graduates (or equivalent) with an educational background in basic science and mathematics.

2. For admission to a 12-month program, the candidate must satisfy one of the following requirements:

(a) Graduation from an accredited or equivalent program in radiography.

(b) Successful completion or challenge of courses in the following prerequisite content areas:

- Radiation physics;
- Human structure and function;
- Radiation protection;
- Medical ethics and law;
- Methods of patient care;
- Medical terminology; and
- Mathematics.

(c) Successful demonstration of the following competencies:

- Practice oral and written communications;
- Perform basic mathematical functions;
- Demonstrate knowledge of human structure and function;
- Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
- Provide basic patient care and cardiopulmonary resuscitation;
- Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
- Apply rules and regulations for radiation safety, detect defects which might pose a radiation hazard, and maintain control, if a radiation accident occurs; and
- Interact with patients and families concerning patients physical and psychological needs.

*E. Continuing Program Evaluation*

1. A process for periodic and systematic review of the program's effectiveness must be documented and reflected in policies.

2. Program evaluation shall include the employment performance of recent graduates.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX F TO PART 75—STANDARDS  
FOR LICENSING RADIOGRAPHERS, NU-  
CLEAR MEDICINE TECHNOLOGISTS,  
AND RADIATION THERAPY TECH-  
NOLOGISTS

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

*A. Licensure*

1. Only eligible applicants who have passed the licensure examination shall be licensed as Radiographers, Nuclear Medicine Technologists, or Radiation Therapy Technologists.

2. Licenses shall be renewed at periodic intervals.

*B. Eligibility*

1. For regular eligibility to take the licensure examination, applicants shall have successfully completed an accredited program of formal education in radiography, nuclear medicine technology, or radiation therapy technology.

2. Special eligibility to take the licensure examination shall be provided for applicants whose training and/or experience are equal to, or in excess of, those of a graduate of an accredited educational program.

*C. Examination*

A criterion-referenced examination in radiography, nuclear medicine technology, or radiation therapy technology shall be utilized to test the knowledge and competencies of applicants.

*D. Continuing Competency*

The licensed Radiographer, Nuclear Medicine Technologist, or Radiation Therapy Technologist shall maintain continuing competency in the area in which he/she is practicing.

*E. Policies and Procedures*

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, ob-

jectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

APPENDIX G TO PART 75—STANDARDS  
FOR LICENSING DENTAL HYGIENISTS  
AND DENTAL ASSISTANTS IN DENTAL  
RADIOGRAPHY

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

Currently, Dental Hygienists are credentialled through individual State licensure processes, all of which include assessment of competence in dental radiography. In all States, Dental Hygienists are required to be licensed prior to practicing. The existing State dental hygiene licensure processes meet the intent and purpose of the Consumer-Patient Radiation Health and Safety Act of 1981 and the standards for licensing Dental Hygienists in dental radiography set forth below.

*A. Licensure/Permit*

1. To those who have passed a licensure or designated dental radiography examination, a license or permit shall be issued by the State entity responsible for credentialing dental personnel.

2. Licenses or permits shall be renewed at periodic intervals.

*B. Eligibility*

1. An individual shall provide proof of graduating student status or graduation from an accredited or approved dental hygiene or dental assisting education program.

2. For dental assistants, special eligibility to take the examination shall be provided to applicants with appropriate combinations of training and/or experience.

*C. Examination*

A criterion-referenced examination in dental radiography shall be utilized to test the knowledge and competencies of applicants.

*D. Continuing Competency*

The Dental Hygienist or Dental Assistant shall be required to maintain continuing

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competency in the area in which he/she is practicing.

*E. Policies and Procedures*

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organiza-

tion to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.